December 3, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
U.S.A.

Re: Docket No. 2004D-0443

Dear Sir/Madam:

We, the Japan Society of Pharmaceutical Machinery and Engineering (JSPME) are pleased to submit you our offers and comments concerning "Guidance for Industry Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations" (Docket No. 2004D-0443). We hope that you will consider our comments, and this guidance will be a very fruitful guidance for assuring product quality and ensuring risk management.

We would be much obliged if you give us FDA review of our comments by letter or e-mail.

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Sincerely,

Katsuhide Terada

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2004D-0443 C14

Comments on "Guidance for Industry Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations"

The Japan Society of Pharmaceutical Machinery and Engineering (JSPME)

It is anticipated that this draft "Guidance" in support of a "Quality Systems Approach" will serve as important and very useful guidance for assuring product quality and ensuring risk management. Based on such philosophy, the Japan Society of Pharmaceutical Machinery and Engineering (JSPME) wishes to hereby submit its comments on the draft Guidance.

1. **General: The purpose of this Guidance should be further clarified. Is the Guidance intended to harmonize with other standards such as ISO, or to visualize FDA's concept described in "Pharmaceutical cGMPs for 21st Century: A Risk-Based Approach" ?**

2. **General: The content of the draft Guidance is very similar to that of ISO, particularly in regard to "Management Responsibilities". The document merely makes mention of the difference between cGMP and the Guidance. Therefore, we suggest that the relationship or differences between the Guidance and standards such as ISO or HACCP, etc., should also be described.**

3. **General: "Management Responsibilities" for quality systems extend not only to product manufacturing but also areas of pharmaceutical development including non- and clinical studies. From such viewpoint, this Guidance should be higher ranked than cGMP or other guidance issued to industry.**

4. **General: As for example in Lines 604-619, incompatibility exists with other standards such as cGMP. Such inconsistencies should be clarified and resolved, and a procedure for reporting to and involving FDA should be clearly developed and described.**

5. **General: Quality systems models introduced in this guidance will be the key concept for "Pharmaceutical cGMPs for 21st Century: A Risk-Based Approach" announced on August 2002. However, Lines 118-125 would**

appear to suggest that the document is not intended to create new expectations, but rather to explain the implementation of comprehensive quality systems. We feel that the necessity for, and/or application of, a quality systems approach should be clearly declared in this document.

6. **Line 116: The scope of this Guidance regarding "manufacturers of components used in the manufacture of these products" should be clarified. For example, is this Guidance applicable for manufacturers producing packaging materials used in PTP or inorganic compounds used in buffer preparation?**

7. **Lines 169-173: Clear definition of "Risk Management" and "Risk Assessment" should beprovided. A description of the two terms is given in Lines 169-173 only.**

8. **Lines 713-723: Guidance such as SUPAC should be added in "Reference".**